

## **REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the reasons that follow. By the present communication, claims 111 and 119 are amended, claim 122 is canceled, and claim 123 is newly added. Such amendments do not add new matter, nor do they require a new search of the literature. After amending the claims as set forth above, claims 81-123 will be pending, and under examination, in this application.

### **Examiner Interview**

Applicant thanks Examiner Haider for courtesies extended during the interview of the present matter on June 9, 2010. Present for the interview were Examiner Haider and Applicant's representatives Robert Whitehouse (inventor), Steve Davis and Jeff Lompfrey. The differences between the cited references and the claimed invention were discussed, and Applicants agreed to provide information regarding the basis for the differences as discussed. No overall agreement was reached.

### **The "Whitehouse Declaration"**

Attached hereto is a declaration from Dr. R. Whitehouse which provides probative evidence regarding the Applicants claimed invention and how it differs from the references as cited by the Examiner. A more detailed discussion of the topics addressed by the Whitehouse Declaration is provided in response to the rejections below.

### **Claim Rejections – 35 USC § 103**

#### *Noda and Saito*

Claims 81-87, 99-110, 119 and 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Noda et al.* (US 2002/0143136) as evidenced by *Saito et al.* (Polymer International).

In the Office Action, the Examiner appears to imply that because Noda teaches laminate compositions, the presently claimed articles having an *adhesive* composition are unpatentable. However, Applicant asserts that the laminates of Noda are *not* adhesives, and do not render obvious the presently claimed invention. As support for this position, Applicant provides the Whitehouse Declaration which is attached hereto.

As set forth in claim 1, the article includes: “a substrate having a surface; and an *adhesive* composition supported by the surface of the substrate, wherein the adhesive composition comprises a PHA, the PHA being poly 3-hydroxybutyrate-co-4-hydroxybutyrate having a glass transition temperature from about -30°C to about -5°C.” The present specification, in paragraphs 35-37 describes, in detail, adhesive compositions:

[0035] In certain embodiments, a PHA adhesive composition can have a relatively low surface tack. For example, in some embodiments, a PHA adhesive composition can be substantially non-tacky to the touch prior to its use in forming an adhesive bond between two surfaces. In certain embodiments, a PHA adhesive composition can have a surface tack time value of at most about 15 seconds...prior to its use in forming an adhesive bond between two surfaces.

[0036] As referred to herein, the surface tack time value of a PHA adhesive composition is determined as follows. A galvanised steel washer having mass of 13.85 grams (g) with external diameter 38.17 millimeter (mm) and internal diameter 13.41 millimeter (mm) is placed onto a horizontally displaced surface that is coated with the PHA adhesive composition. The surface is then inverted, so that gravitational force on the object and the adhesive force of the composition on the object oppose each another. The time required for the object to fall from the surface is the surface tack time value of the PHA composition. In general, a PHA adhesive composition having a lower surface tack will have a shorter surface tack time value than a PHA adhesive composition having a higher surface tack.

[0037] In some embodiments, a PHA composition can form a relatively strong bond between two surface when exposed to a relatively low laminating pressure. For example, in certain embodiments, a PHA adhesive composition can form an adhesive bond between two surfaces with a peel bond strength of at least about 10 Newtons per square meter

(N/m<sup>2</sup>)...when the PHA composition is exposed to a laminating pressure of at most about 100 pounds per square inch gauge (psig)...

Emphasis added.

The description provided above is further evidenced by the Whitehouse Declaration which describes the use of the term “adhesive” and the physical interactions during adhesion. As described in the Whitehouse Declaration, the surface energy of a substrate should be higher than that of the adhesive, to obtain good adhesion. The presently claimed PHA adhesives (which are based upon poly 3-hydroxybutyrate-co-4-hydroxybutyrate) all have a T<sub>g</sub> from about -30°C to about -5°C, the importance of which is illustrated by Examples 10-22. Thus, the Whitehouse Declaration provides further discussion and clarification the importance of the claimed T<sub>g</sub> range in describing the adhesives, as set forth in the specification and examples.

Furthermore, the Whitehouse Declaration provides additional discuss to show that the PHAs described by Noda are *not* adhesives as that term is used in the present application. As found in paragraph 8 of the Whitehouse Declaration, when PLA is blended with poly(3-hydroxybutyrate-co-11%-4-hydroxybutyrate) the materials produced do not exhibit an open time or a tack time. Furthermore, PLA alone does not exhibit either an open time or a tack time. Accordingly, even if the blends of Noda were to be modified as suggested by the Examiner, they would not be adhesives, and therefore they would not render the presently claimed invention obvious.

Noda describes films or laminates of a blend of PHA polymers that are environmentally degradable. Paragraph 14. Noda requires at least two such polymers: the first is a polyhydroxyalkanoate copolymer and the second is polylactic acid. *Id.* Both such polymers are PHAs. In summarizing the invention of Noda, it is stated in paragraph 14 that:

The present invention is directed toward films or laminates comprising environmentally degradable polymers. A first polymer is biodegradable and is a polyhydroxyalkanoate copolymer as set forth infra. A second polymer is an environmentally degradable

PLA polymer as set forth *infra*. The polyhydroxyalkanoate copolymer will make the film or laminate rapidly environmentally degradable. The second PLA polymer will make the polymer blend processable and help to decrease stickiness that is commonly associated with polyhydroxyalkanoate polymers.

Thus, according to Noda's own description, an object of the invention, through incorporation of a PLA polymer, is to decrease the stickiness associated with PHAs. To the extent that stickiness is required for an adhesive, Noda itself belies an interpretation of the reference that the blends taught by the reference are adhesives, and the Whitehouse Declaration confirms this.

As illustrated in paragraph 8 of the Whitehouse Declaration, the open time and tack time adhesive properties were analyzed for PLA, and blends of PLA with a 3-hydroxybutyrate-co-4-hydroxybutyrate.<sup>1</sup> The Declaration shows that none of the tested materials exhibited an open time or a tack time and accordingly, provides further evidence that the PLA blends of Noda are not adhesives within the meaning of the present application.

Noda also describes the preparation of the films and laminates, a description which does not include that of an adhesive. As described by Noda, the films may be cast or blown and can be a single thermoplastic or a blend thermoplastic from a single extruder and single die. Paragraph 67. With respect to laminates, Noda teaches that coextrusion processes are preferably employed. Such processes require more than one extruder and either a coextrusion feedblock or multi-manifold die system to achieve the multilayer film structure. Paragraph 68. Noda then describes several such systems for coextrusion, noting that "[t]he flow channels are designed such that at their point of confluence, the *materials flow together* at the same flow rate and pressure eliminating interfacial stress and flow instabilities...It is *important* in such processes that the *melt* viscosities and *melt* temperatures of the materials do not differ too greatly..."

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<sup>1</sup> Interestingly, the Examiner asserts in paragraph 7 of the Non-Final Office Action, that Noda shows a preference for 3HB in the first RRMU and 4HB in the second RRMU. Thus, the Whitehouse Declaration provides further evidence that, contrary to the Examiner's assertion of adhesive properties in Noda, the blends described by Noda are not adhesives as that term is presently used in the claimed invention.

Paragraph 69, emphasis added. Alternatively, a multi-manifold or vane die is used, where each melt stream has its own manifold in the die. The melt streams are married near the die exit with each melt stream at full die width. “Movable vanes provide adjustability...allowing the *melts* to flow together at the same linear flow rate. Paragraph 70.

As described by Noda, the “laminates” are film layers that are melted together. The extrusion processes described by Noda rely on the intermixing of the polymer interfaces as they are extruded from the dies. There is no discussion of the supporting of an adhesive on one surface and bringing another into close proximity such that the two surfaces are adhered by the adhesive, as is described by the instant specification and claims.

In fact, as illustrated above with respect to adhesives in the present specification, the Noda laminates are incapable of being adhesives. The present adhesives are described as either being tacky and having adhesion due to the tackiness or they are contact adhesives that may not be tacky to the touch but adhere upon application of light pressure. Conversely, Noda teaches that the PHA blends require melt bonding to form the laminate structure. No such melting is required of an adhesive according to the present claims and specification.

The reasons for the melt mixing of the polymers of Noda are clearly set forth in the Whitehouse Declaration, paragraph 6. As shown, the surface energy mis-match results in non-adhesion of the PHA to the PLA laminates of Noda. Instead, the heating of the PLA by the hot PHA distorts the PLA, with the distorted PLA thus inhibiting adhesion when contacted by the hot PHA. Rather, polymer strand mixing at the interface of the PHA and the PLA is needed to make the laminate.

Applicant also points out, as did the Examiner, that Noda shows a preference for a 3-hydroxybutyrate and 4-hydroxybutyrate co-polymer in the blends with polylactic acid. Yet, Noda fails to find any adhesive property for the co-polymer alone. Instead, Noda teaches that a blend of polylactic acid must be utilized with the polymer and that co-extrusion processes are required to form laminates. The layering of the polymers in the laminates is entirely due to mixing of the

melt phases at the different polymer interfaces as they exit an extrusion die. In other words, Noda is actually leading the person of ordinary skill in the art away from the presently claimed invention in that the overwhelming teaching is that melt blending is needed to prepare a laminate, not adhesion of two layers by an adhesive layer.

Saito, the other reference relied upon by the Examiner, similarly fails to teach or suggest the use of poly 3-hydroxybutyrate-co-4-hydroxybutyrate in an adhesive composition. Saito is directed the synthesis of poly 3-hydroxybutyrate-co-4-hydroxybutyrate and its properties. Saito teaches the glass transition temperatures of various ratios of the individual monomeric units to one another, and that the co-polymers have varying thermal and physical properties, and that they are biodegradable. However, there is no suggestion or teaching of an adhesive that includes a PHA that is poly 3-hydroxybutyrate-co-4-hydroxybutyrate having a glass transition temperature from about -30 °C to about -5 °C. In fact, Saito entirely lacks any discussion of adhesive properties.

#### *Method Claims*

Separately from the article claims discussed above, Applicant addresses the method claims. As set forth in independent claim 119, a method is provided “comprising pressing a PHA between at least two surfaces to form a pressed PHA; wherein the PHA is poly 3-hydroxybutyrate-co-4-hydroxybutyrate having a glass transition temperature from about -30 °C to about -10 °C.” Applicant asserts that such a method is neither taught nor suggested by Noda or Saito.

As discussed above, Noda is directed to laminates that are produced as they exit an extruder and in which the adjacent layers are married by a melt blending of the layers. There is no discussion of a pressing step in Noda, because the films are then blown or cast. Furthermore, there is no pressing step in Noda because the layers are already joined by the melt process and there is no reason to press to ensure adherence of the layers by pressing because they are already melted and joined at the interface. Furthermore, because Saito fails to teach or suggest

adhesives, there can be no teaching or suggestion of pressing two surfaces to adhere them together. Thus, even the combination of Noda and Saito fails to teach or suggest the presently claimed methods.

*Summary*

Because Noda and Saito fails to teach or suggest adhesive compositions, and because Noda fails to teach or suggest the PHA of the instant adhesive compositions, Noda and Saito, even in combination, do not render the presently claimed articles and methods obvious. Having overcome the pending rejection, Applicant respectfully requests that the rejection be withdrawn and the application moved toward issuance.

*Noda, Saito, and Noda II*

Claims 88-98, 111-118, 120, and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noda *et al.* (US 2002/0143136) as evidenced by Saito *et al.* (*Polymer International*), in further view of US 6,174,990, issued to Noda *et al.* (*i.e.* “Noda II”).

With respect to this rejection, Applicant stands by the comments above showing that Noda and Saito fail to teach or suggest an adhesive composition. Applicant also submits that Noda II, likewise fails.

Noda II describes materials that are prepared from a PHA co-monomer having a first repeat unit and a second repeat unit. The first repeat unit is based upon a generic PHA monomer that can be any one of 6 different repeat units, and the second repeat unit is derived from 3-hydroxy-4-methylvalerate. Col. 5, line 56 – col. 6, line 5. Applicant submits that the 3-hydroxy-4-methylvalerate materials *are not* adhesives, in and of themselves. This is shown by both the present application and is further supported by Kaufmann (U.S. 5,169,889), as submitted with the IDS on June 22, 2004.

As described in Example 3 of the present specification, and as further elaborated upon in the Whitehouse Declaration, PHA compositions containing the 3-hydroxyvalerate are not adhesives. Example 3 shows that a PHA composition of poly(3HB)-co-8%-(3HV) has a Tg of +2°C. The PHA composition of Example 3 is observed to exhibit *no* adhesion. It is noteworthy that the Tg of the PHA in Example 3 is outside the claimed Tg range of -5°C to -30°C.

In Kaufmann, it is shown that for polyhydroxybutyrate-co-hydroxyvalerate to exhibit adhesive properties, at least 10% by weight must be a polar tackifier having a Ring and Ball softening point greater than about 60°C. *See* col. 1, lines 65-66.

Therefore, although Noda II describes the use of such a copolymer as an adhesive (beginning at H. in col. 23, line 53), the evidence provided in the present application and in Kaufman shows that as the term “adhesive” is presently used, compounds containing 3-hydroxyvalerate are not adhesives. Furthermore, Noda simply fails to provide any teaching or suggestion of the narrowly claimed present invention that dictates a particular PHA (poly 3-hydroxybutyrate-co-4-hydroxybutyrate) for use in the adhesive composition.

After reviewing Noda, Saito, and Noda II, the person of ordinary skill in the art is not directed to the presently claimed invention. Noda actually directs that melt processing, as a result of extrusion, is required to prepare a laminated article. Saito fails to recognize any type of adhesive property for a PHA. Finally, Noda II requires the presence of 3-hydroxy-4-methylvalerate, which is not encompassed by the claims. In view of such explicit direction that is not inclusive of the presently claimed invention, there can be no teaching or suggestion of the present invention, or motivation provided to the person of ordinary skill in the art to practice the present invention. Any such suggestion is clearly grounded upon impermissible hindsight reconstruction.

#### *Hindsight Reconstruction*



That hindsight reconstruction is improper is apparent from the PTO's own rules. For instance, § 2141.01(III) of the MPEP notes that the "content of the prior art is determined at the time the invention was made to avoid hindsight," and §707.07(f) states that

...any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, *and does not include knowledge gleaned only from the applicant's disclosure*, such a reconstruction is proper.

(Emphasis added.) Similarly, the "tendency to resort to 'hindsight' based upon Applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, *impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.*" MPEP § 2142 (emphasis added).

The PTO's review court likewise has mandated that "a prima facie case of obviousness for a chemical compound...begins with the reasoned identification of a lead compound." *Eisai Co. Ltd. v. Dr. Reddy's Laboratories Ltd.*, 533 F.3d 1353,1359 (Fed. Cir. 2008) (copy appended). From this perspective, substantiating a finding of obviousness can be based on structural similarity along with some "motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound." *Id.* at 1357.

Section 2143.01 (III) of the MPEP explains that "the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." This is wholly consistent with the position taken by the Federal Circuit in *Eisai*. The prior art must form the basis for the reasons to modify a particular compound, and the prior art must provide reason to one of skill in the art to select a particular compound for modification.

In the present application, the Examiner has identified the PHAs of Noda and Saito as providing a basis to use them as adhesives (i.e. a lead compound). However, Saito utterly fails to

describe the polymers as such and Noda states that they only form laminates from the melt. The Examiner then turns to Noda II, which although descriptive of adhesives, requires a different chemical formula that is not a preferred compound in either Noda or Saito. Thus, there is no motivation in the lead compound to make the Examiner's proposed combination to find all of the elements of the presently claimed invention.

Applicant is entirely cognizant that any rejection based upon obviousness is, to some extent, based upon hindsight reconstruction, in that familiarity with the claims at issue must be used to choose appropriate references upon which to base the rejection. However, as illustrated above, "...only knowledge which was within the level of ordinary skill at the time the claimed invention was made..." can be used in conjunction with the teachings within those references to assemble the rejection itself. As set forth above, the knowledge at the time was that melt processing was required to make a laminate and that adhesives required 3-hydroxy-4-methylvalerate. As illustrated above, Noda, Saito, and Noda II, are at odds with one another in a number of respective teachings. Just because the Examiner finds various parts of the claimed invention in isolation within the references, does not provide a basis for obviousness unless they suggest the desirability of the combination.

*Method Claims 111-118, 120, and 121*

Separately from the article claims discussed above, Applicant addresses the method claims. As set forth in independent claim 111, a method is provided "comprising applying a PHA solution comprising a solvent and a PHA to a substrate surface to form a layer of the PHA solution; removing at least some of the solvent to form a PHA adhesive composition on the substrate surface; wherein the PHA is a poly 3-hydroxybutyrate-co-4-hydroxybutyrate having a glass transition temperature from about -30 °C to about -5 °C." Applicant asserts that such a method is neither taught nor suggested by Noda, Noda II or Saito, and there is no motivation to combine the disparate teachings of the cited references to arrive at the presently claimed methods.

As discussed above, even the combination of Noda and Saito fails to teach or suggest the presently claimed methods. Because Noda teaches the direct formation of a laminate from an extruder during the melt phase of all of the individual polymers being layered, there can simply be no teaching or suggestion of the method that involves applying a *PHA solution* to a substrate, removing at least some of the solvent to form a PHA adhesive composition. Also as discussed above, Saito fails to teach or suggest adhesive compositions in any manner. Finally, Noda II does describe adhesive compositions and their use, however the adhesive compositions require the presence of 3-hydroxy-4-methylvalerate, which is not encompassed by the presently claimed methods.

As such, because the method of Noda is devoid of any suggestion or teaching of adhesive compositions, and Saito does nothing to fill this void, there is no reason to combine either of Noda and Saito with Noda II to find the presently claimed PHA in an adhesive composition.

#### *Summary*

For at the forgoing reasons, Applicant submits that a case of obviousness has not been supported and Applicant requests that the Examiner withdraw the pending rejection and allow the application to move forward to issuance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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